

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/005930

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl⁷ A61K45/00, 31/55, 39/395, 48/00, A61P7/00, 11/00,
29/00//C07D403/06, 401/14, 417/14, 471/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl⁷ A61K45/00-45/06, 31/00-31/80, 39/395, 48/00, A61P1/00-43/00,
C07D403/00-403/14, 401/00-401/14, 417/00-417/14, 471/00-471/04

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
CAPLUS (STN), REGISTRY (STN), MEDLINE (STN), EMBASE (STN), BIOSIS (STN),
BIOTECHABS (STN), WPI (DIALOG), JSTPLUS (JOIS), JMEDPLUS (JOIS),

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 02/061087 A2 (LIFESPAN BIOSCIENCES, INC.), 08 August, 2002 (08.08.02), Claims; Par. Nos. [0265] to [0266]; sequence Nos. 272, 273. & US 2003/0113798 A1 & AU 2002248235 A1	1-4, 14, 18-20 5-9, 11
Y A	BARNES, P.J. New therapies for chronic obstructive pulmonary disease. Thorax, 1998, 53, pages 137 to 147, full text	1-4, 14, 18-20 5-9, 11
Y A	BEERS, M.H. et al. (ed.) THE MERCK MANUAL OF DIAGNOSIS AND THERAPY. 17th Edition. 1999, ISBN 0911910-10-7, ISSN 0076-6526, pages 555 to 582, particularly, CHRONIC OBSTRUCTIVE PULMONARY DISEASE	1-4, 14, 18-20 5-9, 11

☒ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
13 July, 2004 (13.07.04)

Date of mailing of the international search report
03 August, 2004 (03.08.04)

Name and mailing address of the ISA/
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	WITKO-SARAT, V. et al., Neutrophils: Molecules, Functions and Pathophysiological Aspects. Laboratory Investigation, 2000, 80(5), pages 617 to 653, full text	1-4, 14, 18-20 5-9, 11
A	HEIBER, M. et al., Isolation of Three Novel Human Encoding G Protein-Coupled Receptors. DNA and Cell Biology, 1995, 14(1), pages 25 to 35	1-9, 11, 14, 18-20
A	MAHADEVAN, M.S. et al., Isolation of Novel G Protein-Coupled Receptor (GPR4) Localized to Chromosome 19q13.3. Genomics, 1995, 30, pages 84 to 88	1-9, 11, 14, 18-20
A	WO 00/22129 A1 (ARENA PHARMACEUTICALS, INC.), 20 April, 2000 (20.04.00), & AU 9964307 A & EP 1121431 A1 & US 2003/0023069 A1 & CN 1398298 A & JP 2003-531565 A	1-9, 11, 14, 18-20
A	EP 325755 A1 (KYOWA HAKKO KOGYO CO., LTD.), 02 August, 1989 (02.08.89), & JP 1-308274 A & AU 8826711 A & US 4994463 A & US 5143922 A & US 5302602 A	5-9, 11
A	JP 6-228065 A (Kyowa Hakko Kogyo Co., Ltd.), 16 August, 1994 (16.08.94), & EP 549352 A2 & US 5378701 A & US 5478840 A	5-9, 11
A	JP 9-40662 A (Kyowa Hakko Kogyo Co., Ltd.), 10 February, 1997 (10.02.97), (Family: none)	5-9, 11
P, Y	WO 2004/017994 A1 (Kyowa Hakko Kogyo Co., Ltd.), 04 March, 2004 (04.03.04), Full text (Family: none)	1-9, 11, 14, 18-20
P, Y	WO 2004/017995 A1 (Kyowa Hakko Kogyo Co., Ltd.), 04 March, 2004 (04.03.04), Full text (Family: none)	1-9, 11, 14, 18-20

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Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:

a. type of material

☐

a sequence listing

☒

table(s) related to the sequence listing

b. format of material

☐

in written format

☒

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed

☒

filed together with the international application in computer readable form

☐

furnished subsequently to this Authority for the purposes of search

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 10 and 15-17

because they relate to subject matter not required to be searched by this Authority, namely:

The invention of claims 10 and 15-17 pertains to methods for treatment of a human body by therapy (PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv)).

2. ☒ Claims Nos.: 12 and 13

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

The invention of claims 12 and 13 is directed to a preventive and/or therapeutic agent for neutrophil inflammation disease, comprising as an active ingredient a compound represented by the formula (II) in claim 12.

The scope of compounds comprehended (continued to extra sheet)

3. ☐ Claims Nos.:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

With respect to the recitation of claims 1-9, 11-14 and 18-20, it appears that although various substances are mentioned as active ingredients therein, the technical matter common to them is a prevention and/or treatment of neutrophil inflammation disease.

However, the prevention or treatment of neutrophil inflammation disease is widely known by persons skilled in the art to which the invention pertains as described in the cited references. Also, the active ingredients are publicly known by persons skilled in the art to which the invention pertains as described in the cited references. Therefore, it cannot be stated that through the (continued to extra sheet)

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

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Continuation of B. FIELDS SEARCHED

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DDBJ/GanBank/EMBL, SwissProt/PIR/PDB, GeneSeq

Continuation of Box No.II-2 of continuation of first sheet(2)

by the formula (II) ranges wide, and the matter common thereto is only an imidazole ring, an aromatic 6-membered ring formed through condensation thereto and a methylene group portion substituted for 1-position of imidazole ring. However, since this is publicly known (see, for example, JP 2002-30085 A), this chemical structure is not so novel as to be able to satisfactorily identify the invention. Moreover, with respect to the use thereof, it cannot be stated that whether the compound of the above chemical structure is generally effective in the prevention or treatment of neutrophil inflammation disease is not obvious to persons skilled in the art to which the invention pertains. Further, in the description, the applicability to the above use is not ascertained. Consequently, neither is the invention identified by the use, nor the invention is supported by the description.

Therefore, the invention of claims 12 and 13 is neither clearly and briefly described nor fully supported by the description, so that the provisions prescribed in PCT Article 5 and Article 6 are not satisfied.

This international search report has not been established in respect of the invention of claims 12 and 13 because it appears that the description, claims and drawings do not satisfy the prescribed requirements to such an extent that no meaningful search can be carried out (PCT Article 17(2)(a)(ii)).

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Continuation of Box No. III of continuation of first sheet (2)

above technical matters, there is a technical relationship involving the same or corresponding special technical features among these inventions.

In the present invention, it should be construed that the special technical feature resides in a combination of particular active ingredient and disease. Accordingly, it appears that the inventions of claims 1-9, 11-14 and 18-20 of this application consist of the following eight inventions not being in mutual relationship satisfying the requirement of unity of invention:

a) invention of claims 1, 2, 14 and 18 as well as within the invention of claim 4, part falling under the category 1) and part corresponding to SEQ ID No. 11 under the category 4) and within the invention of claim 20, part using these;

b) within the invention of claim 3, part falling under the category 1) and part corresponding to SEQ ID No. 12 under the category 4) and within the invention of claim 19, part using these;

c) within the invention of claim 3, part falling under the category 2) and part corresponding to SEQ ID No. 14 under the category 4) and within the invention of claim 19, part using these;

d) within the invention of claim 3, part falling under the category 3) and part corresponding to SEQ ID No. 18 under the category 4) and within the invention of claim 19, part using these;

e) within the invention of claim 4, part falling under the category 2) and part corresponding to SEQ ID No. 13 under the category 4) and within the invention of claim 20, part using these;

f) within the invention of claim 4, part falling under the category 3) and part corresponding to SEQ ID No. 17 under the category 4) and within the invention of claim 20, part using these;

g) invention of claims 5-9 and 11; and

h) invention of claims 12 and 13.

With respect to Claims 1, 2 and 14

In claim 1, the active ingredient of preventive and/or therapeutic agent for neutrophil inflammation disease is recited as being a "substance capable of inhibiting the function relating to signal transmission of a protein having an amino acid sequence of SEQ ID No. 11". However, what specific chemical structures are comprehended in the active ingredient is neither apparent from the recitation nor clearly defined in the description, so that the matter is not obvious to persons skilled in the art to which the invention pertains.

Therefore, it cannot be stated that the whole of the invention of claim 1 is clearly and briefly specified by the recitation and further that the description of the descriptive portion of the application is made so as to support the whole of the invention (PCT Article 5 and Article 6).

Same applies to the inventions of claims 2 and 14 quoting claim 1.

Thus, as the recitation of the claims and the description of the descriptive portion of this application fail to satisfy the prescribed requirements, in the preparation of international search report on the inventions of these claims, the subject of the prior art search has been limited to rational scope based on the recitation of the claims and the description of the descriptive portion of the application.

A. 発明の属する分野の分類 (国際特許分類 (IPC)) Int. Cl ⁷ A61K45/00, 31/55, 39/395, 48/00, A61P7/00, 11/00, 29/00 // C07D403/06, 401/14, 417/14, 471/04		
B. 調査を行った分野 調査を行った最小限資料 (国際特許分類 (IPC)) Int. Cl ⁷ A61K45/00-45/06, 31/00-31/80, 39/395, 48/00, A61P1/00-43/00, C07D403/00-403/14, 401/00-401/14, 417/00-417/14, 471/00-471/04		
最小限資料以外の資料で調査を行った分野に含まれるもの		
国際調査で使用した電子データベース (データベースの名称、調査に使用した用語) CAPLUS (STN), REGISTRY (STN), MEDLINE (STN), EMBASE (STN), BIOSIS (STN), BIOTECHABS (STN), WPI (DIALOG), JSTPLUS (JOIS), JMEDPLUS (JOIS), DDBJ/GanBank/EMBL, SwissProt/PIR/PDB, GeneSeq		
C. 関連すると認められる文献		
引用文献の カテゴリー*	引用文献名 及び一部の箇所が関連するときは、その関連する箇所の表示	関連する 請求の範囲の番号
X A	WO 02/061087 A2 (LIFESPAN BIOSCIENCES, INC.) 2002. 08. 08, 請求の範囲, [265]-[266], 配列番号272, 273, & US 2003/0113798 A1 & AU 2002248235 A1	1-4, 14, 18-20 5-9, 11
Y A	BARNES, P. J. New therapies for chronic obstructive pulmonary disease. Thorax, 1998, 53, pp.137-147, 全文参照	1-4, 14, 18-20 5-9, 11
<input checked="" type="checkbox"/> C欄の続きにも文献が列挙されている。 <input type="checkbox"/> パテントファミリーに関する別紙を参照。		
* 引用文献のカテゴリー 「A」 特に関連のある文献ではなく、一般的技術水準を示すもの 「E」 国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの 「L」 優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献 (理由を付す) 「O」 口頭による開示、使用、展示等に言及する文献 「P」 国際出願日前で、かつ優先権の主張の基礎となる出願日の後に公表された文献 「T」 国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの 「X」 特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの 「Y」 特に関連のある文献であって、当該文献と他の1以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの 「&」 同一パテントファミリー文献		
国際調査を完了した日 13. 07. 2004		国際調査報告の発送日 03. 8. 2004
国際調査機関の名称及びあて先 日本国特許庁 (ISA/JP) 郵便番号100-8915 東京都千代田区霞が関三丁目4番3号		特許庁審査官 (権限のある職員) 荒木 英 則 電話番号 03-3581-1101 内線 3450

C (続き) . 関連すると認められる文献		
引用文献の カテゴリー*	引用文献名 及び一部の箇所が関連するときは、その関連する箇所の表示	関連する 請求の範囲の番号
Y	BEERS, M. H., <i>et al.</i> (ed.) THE MERCK MANUAL OF DIAGNOSIS AND THERAPY. 17th Edition. 1999, ISBN 0911910-10-7,	1-4, 14, 18-20
A	ISSN 0076-6526, pp.555-582, 特にCHRONIC OBSTRUCTIVE PULMONARY DISEASEの項	5-9, 11
Y	WITKO-SARAT, V., <i>et al.</i> Neutrophils: Molecules, Functions and Pathophysiological Aspects. Laboratory Investigation, 2000, 80(5), pp.617-653, 全文参照	1-4, 14, 18-20
A		5-9, 11
A	HEIBER, M., <i>et al.</i> Isolation of Three Novel Human Encoding G Protein-Coupled Receptors. DNA and Cell Biology, 1995, 14(1), pp.25-35	1-9, 11, 14, 18-20
A	MAHADEVAN, M. S., <i>et al.</i> Isolation of a Novel G Protein-Coupled Receptor (GPR4) Localized to Chromosome 19q13.3. Genomics, 1995, 30, pp.84-88	1-9, 11, 14, 18-20
A	WO 00/22129 A1 (ARENA PHARMACEUTICALS, INC.) 2000.04.20, & AU 9964307 A & EP 1121431 A1 & US 2003/0023069 A1 & CN 1398298 A & JP 2003-531565 A	1-9, 11, 14, 18-20
A	EP 325755 A1 (KYOWA HAKKO KOGYO CO., LTD.) 1989.08.02, & JP 1-308274 A & AU 8826711 A & US 4994463 A & US 5143922 A & US 5302602 A	5-9, 11
A	JP 6-228065 A (協和醗酵工業株式会社) 1994.08.16, & EP 549352 A2 & US 5378701 A & US 5478840 A	5-9, 11
A	JP 9-40662 A (協和醗酵工業株式会社) 1997.02.10 (ファミリーなし)	5-9, 11
P Y	WO 2004/017994 A1 (協和醗酵工業株式会社) 2004.03.04, 全文参照 (ファミリーなし)	1-9, 11, 14, 18-20
P Y	WO 2004/017995 A1 (協和醗酵工業株式会社) 2004.03.04, 全文参照 (ファミリーなし)	1-9, 11, 14, 18-20

第I欄 ニュクレオチド又はアミノ酸配列 (第1ページの1. bの続き)

1. この国際出願で開示されかつ請求の範囲に係る発明に必要なヌクレオチド又はアミノ酸配列に関して、以下に基づき国際調査を行った。

a. タイプ ☐ 配列表

☒ 配列表に関連するテーブル

b. フォーマット ☐ 書面

☒ コンピュータ読み取り可能な形式

c. 提出時期 ☐ 出願時の国際出願に含まれる

☒ この国際出願と共にコンピュータ読み取り可能な形式により提出された

☐ 出願後に、調査のために、この国際調査機関に提出された

2. ☐ さらに、配列表又は配列表に関連するテーブルを提出した場合に、出願後に提出した配列若しくは追加して提出した配列が出願時に提出した配列と同一である旨、又は、出願時の開示を超える事項を含まない旨の陳述書の提出があった。

3. 補足意見:

法第8条第3項（PCT17条(2)(a)）の規定により、この国際調査報告は次の理由により請求の範囲の一部について作成しなかった。

- 第Ⅲ欄 発明の単一性が欠如しているときの意見 (第1ページの3の続き)

(続葉に続く。)

- ☐ 追加調査手数料の納付と共に出願人から異議申立てがあった。
- ☒ 追加調査手数料の納付と共に出願人から異議申立てがなかった。

第Ⅱ欄の2. の続きについて

わずかにイミダゾール環、これに縮合してなる芳香族六員環及びイミダゾール環の1位に置換されるメチレン基の部分のみである。しかし、これは公知のものであるから（例えば、JP 2002-30085 Aを参照のこと。）、かかる化学構造は発明を十分に特定し得るほど新規なものではない。また、その用途に関しても、かかる化学構造を有する化合物が一般に好中球性炎症疾患の予防や治療に有効であるということが当業者に自明であるとはいえず、かつ、明細書において当該用途に利用可能であることについて確認されているものでもないから、かかる用途により発明が特定され得るものではなく、かつ、明細書において当該発明が裏付けられたものでもない。

してみれば、請求の範囲12及び13に係る発明は明確かつ簡潔に記載されたものではなく、明細書により十分裏付けがなされたものでもないから、PCT5条及び6条の規定を満足しないものとなっている。

そして、請求の範囲12及び13に係る発明は、その明細書、請求の範囲又は図面が有意義な調査を行うことができる程度に所定の要件を満たしていないと認められるので、国際調査報告の作成対象外とした。（PCT17条(2)(a)(ii)）

第Ⅲ欄の続きについて

そして、本願発明においては、特別の技術的特徴とは、具体的な有効成分と疾患との組み合わせにあるものというべきである。してみれば、本願の請求の範囲1-9, 11-14, 18-20に係る発明は、相互に発明の単一性を有さない、以下の8発明からなるものと認められる。

- a) 請求の範囲1, 2, 14及び18に係る発明、並びに、請求の範囲4に係る発明のうち、1)に該当する部分及び4)のうち配列番号11に対応する部分、及び請求の範囲20に係る発明のうちこれらを使用する部分
- b) 請求の範囲3に係る発明のうち、1)に該当する部分及び4)のうち配列番号12に対応する部分、並びに請求の範囲19に係る発明のうちこれらを使用する部分
- c) 請求の範囲3に係る発明のうち、2)に該当する部分及び4)のうち配列番号14に対応する部分、並びに請求の範囲19に係る発明のうちこれらを使用する部分
- d) 請求の範囲3に係る発明のうち、3)に該当する部分及び4)のうち配列番号18に対応する部分、並びに請求の範囲19に係る発明のうちこれらを使用する部分
- e) 請求の範囲4に係る発明のうち、2)に該当する部分及び4)のうち配列番号13に対応する部分、並びに請求の範囲20に係る発明のうちこれらを使用する部分
- f) 請求の範囲4に係る発明のうち、3)に該当する部分及び4)のうち配列番号17に対応する部分、並びに請求の範囲20に係る発明のうちこれらを使用する部分
- g) 請求の範囲5-9, 11に係る発明
- h) 請求の範囲12, 13に係る発明

請求の範囲 1, 2, 14 について

請求の範囲 1 では、好中球性炎症疾患の予防および/または治療剤の有効成分が「配列番号 11 記載のアミノ酸配列を有する蛋白質のシグナル伝達に関する機能を抑制する物質」であるとされるが、かかる記載によっては有効成分として具体的にいかなる化学構造のものが包含されるものであるのかが明らかではなく、また、明細書にも明確に定義されておらず、当業者にとり自明なものであるともいえない。

してみれば、かかる記載によっては請求の範囲 1 に係る発明の全体を明確かつ簡潔に記載されたものとはいえず、かつ、明細書の記載もかかる発明の全体を裏付けるように記載されたものとはいふことができない (PCT 5 条及び 6 条)。

また、請求の範囲 1 を引用する請求の範囲 2 及び 14 に係る発明についても同様である。

そして、本願はこのような請求の範囲及び明細書の記載が所定の要件を満足しないものであるから、これらの請求の範囲に係る発明に対する国際調査報告の作成に際しては、請求の範囲及び明細書の記載に基づき合理的な範囲のみを先行技術調査の対象とした。